

Remarks

This application has been carefully reviewed in light of the Office Action dated June 13, 2007. Claims 15 to 52 remain in the application, of which Claims 15, 46 and 47 are the independent claims. Claims 51 and 52 have been newly added herein. Reconsideration and further examination are respectfully requested.

New Claims 51 and 52 have been added herein, directed to delivery capsules in which one of the two layers of material (*i.e.*, of the dividing wall or septum) comprises a different materials than the other of the two layers of material, and in which each chamber is defined by an outer shell of material and a corresponding one of the two layers of material, and wherein each outer shell of material comprises a same material as the corresponding one of the two layers of material. Support for these Claims can be found throughout the application as filed, including, for example, in ¶¶ [0014], [0033] and [0042]. Accordingly, no new matter is believed to have been added to the Application with these amendments. These claims are believed to patentably distinct over the applied references for at least the same reasons as the independent claim from which they depend, and furthermore as the applied references are nowhere seen to disclose or suggest a dividing wall or septum having two layers of two different materials.

Turning to the rejections, Claims 15 to 50 were rejected under 35 U.S.C. § 103(a) over European Patent Application No. EPO 0 211 079 (“Ueda”) in view of International Patent Application Publication No. WO 97/35537 (“Brown”). Reconsideration and withdrawal of these rejections are respectfully requested.

Independent Claim 15 is directed to a delivery capsule having at least two separate chambers, the capsule including a dividing wall or septum defining in part two separate chambers, wherein the dividing wall or septum comprises two layers of material adhered together with an adhesive material.

Independent Claim 46 is directed to a method of encapsulation comprising supplying two films of material capable of deforming plastically on heating and/or when partially solvated,

heating the films and/or applying solvent; forming the films into suitably shaped capsule portions, supplying respective substances to be encapsulated to capsule portions of each film, supplying a respective film of a dividing septum material to each of the filled capsule portions, and sealing the capsule portions and septum material together to form a capsule having at least two separate chambers.

Independent Claim 47 is directed to encapsulation apparatus comprising means for supplying two films of material to an encapsulation unit, means for plastically deforming each film to form suitably shaped capsule portions, means for supplying respective substances to be encapsulated to the respective capsule portions of each film, means for supplying a respective film of dividing septum material to each of the filled capsule portions, and means for sealing together the capsule portions and septum material to produce a capsule having at least two separate chambers.

The applied references are not seen to disclose or suggest the features of the claimed invention, particularly with respect to at least the features of (i) a dividing wall or a septum having two layers of material adhered together with an adhesive material (as in Claim 15) and (ii) supplying a respective film of a dividing septum material to each of two filled capsule portions (as in Claims 46 and 47).

“To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” MPEP § 2143.03; *see also In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). In this respect, the Office Action concedes that Ueda and Brown are entirely silent as to the particular claim feature of a dividing wall or a septum having two layers of material. Accordingly, as this claim feature is nowhere taught in or suggested in the cited references, the outstanding 35 U.S.C. § 103(a) rejection of Claims 15 to 50 fails to meet the standard for *prima facie* obviousness. Nevertheless, the Office Action contended that “Applicants have not demonstrated any significant patentable distinction between the Ueda delivery capsule and the instant delivery capsule.” Office Action, p. 4. The requirement that the patentable distinction be “significant” is nowhere to be found in the MPEP, the Code or the

Rules. Accordingly, Applicants respectfully request that the outstanding 35 U.S.C. § 103(a) rejection of Claims 15 to 50 be withdrawn.

As discussed in Applicants' previous response, the claimed invention is believed to be patentably distinct over the combination of Ueda and Brown, as nowhere is either of these references seen to disclose (i) a dividing wall or a septum having two layers of material adhered together with an adhesive material or (ii) supplying a respective film of a dividing septum material to each of two filled capsule portions. Ueda is seen to be directed to a multi-chamber capsule divided by *a single film* into a plurality of chambers. *See, e.g.*, Ueda p. 4, ll. 8-20; p. 9, ll. 7-25. More particularly, Ueda teaches a system and method in which films are deformed into cavities in a rotating drum, such that the cavities are filled when the opening to these cavities are in a vertical or substantially vertical position. *See* Ueda, Figure 2; p. 9, ll. 7-25. Alternatively, Ueda discloses filling one cavity when the cavity is in a horizontal position, applying a septum material to the top of this cavity, applying the second filling material to the top of the septum and then applying the second capsule cavity material on top of both the septum and the second filling material. *See* Ueda, p. 10, l. 17 – p. 11, l. 5.

Ueda's multi-chamber capsule, being divided by a *single film*, suffers from a number of deficiencies when compared to a delivery capsule of the claimed invention. For example, a delivery capsule of the claimed invention comprises two capsule cavities that can be *separately filled and sealed* prior to being adhered together, a far more simple and efficient filling process than that of Ueda. Moreover, the two capsule cavities of the claimed delivery capsule can be *partially filled* (in contrast to Ueda and Brown, which both rely on the filling process to deform the film and create the cavities) prior to sealing and adhesion together. The *partially filled* delivery capsule enjoys a greater propensity for distortion of shape (*e.g.*, greater "softness") such that, for example, the capsules may be more easily swallowed. Further, given the importance of the accuracy in delivery capsules, the ability to only partially fill the cavities of the claimed delivery capsules allows for *metered doses*. All of these benefits redound from the claimed

invention's utilization of a dividing wall or a septum having two layers of material; accordingly, none of these benefits are available to a capsule divided by a *single film*, as taught in Ueda.

Brown is not seen to remedy the foregoing deficiency of Ueda. Brown is seen to be generally directed to a method of encapsulation for forming capsules. *See* Brown, Abstract. The capsules are formed by bringing together two opposed capsule halves in the shape of open hemispheres, such that they form a single undivided chamber. *See, e.g.,* Brown, pp. 5-6 (wherein hemispherical indentations on opposing drum receive gelatin ribbons which deform to line said indentations and are brought together to form capsules). Nowhere is Brown seen to disclose or suggest a septum or a dividing wall of any kind, let alone a dividing wall or septum having two layers of material adhered together with an adhesive material.

Accordingly, the applied references, whether taken alone or in combination, are not seen to disclose or suggest the features of independent Claims 15, 46 and 47, particularly with respect to at least the features of (i) a dividing wall or a septum having two layers of material adhered together with an adhesive material, and (ii) supplying a respective film of a dividing septum material to each of two filled capsule portions.

The other claims currently under consideration in the application are dependent from the independent claims discussed above and therefore are believed to be allowable over the applied references for at least the same reasons. Because each dependent claim is deemed to define an additional aspect of the invention, however, the individual consideration of each on its own merits is respectfully requested.

In view of the foregoing amendment and remarks, all of the claims under consideration are believed to be in condition for allowance and such action is respectfully requested at the Examiner's earliest convenience.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502203 and please credit any excess fees to such deposit account.

Application No.: 10/701,293

Applicant's undersigned attorney may be reached in our Orange County office by telephone at 949.851.0633. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

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